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# INFORMATION DISCLOSURE STATEMENT

## BY APPLICANT

Docket: 4239-58054

App: ~~Not yet assigned~~  
09/762,124Applicant: Kovacs *et al.*

Filed: Herewith

Art Unit: ~~Not yet assigned~~  
1634

### U.S. PATENT DOCUMENTS

Init.*		Number	Date	Name	Class	Sub	Filed
gk		5,164,490	11/17/92	Santi <i>et al.</i>	—	—	
		5,442,050	8/15/95	Fishman	—	—	
		5,501,947	3/26/96	Emery <i>et al.</i>	—	—	
		5,519,127	5/21/96	Shah <i>et al.</i>	—	—	
		5,593,836	1/14/97	Niemiec <i>et al.</i>	—	—	
		5,702,901	12/30/97	Cummins <i>et al.</i>	—	—	
		5,776,680	7/7/98	Leibowitz <i>et al.</i>	—	—	
					—	—	

### FOREIGN PATENT DOCUMENTS

		Number	Date	Country	Class	Sub	
gk		PCT/GB91/00869	31/5/91	PCT	—	—	
		PCT/US93/09635	8/10/93	PCT	—	—	

### OTHER DOCUMENTS

gk			Leigh <i>et al.</i> , "Quantitative and qualitative comparison of DNA amplification by PCR with immunofluorescence staining for diagnosis of <i>Pneumocystis carinii</i> pneumonia," <i>J. Clin. Pathol.</i> , 46:140-144, 1993
			Moonens <i>et al.</i> , "Rapid Simple and Nested Polymerase Chain Reaction for the Diagnosis of <i>Pneumocystis carinii</i> pneumonia," <i>Scand. J. Infect. Dis.</i> , 27:358-362, 1995

EXAMINER:

J. Goldberg

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\*Examiner: Initial if considered, whether or not in conformance with MPEP 60; draw line through cite if not in conformance and not considered. Send copy.

<b>INFORMATION DISCLOSURE STATEMENT</b>  <b>BY APPLICANT</b>	Docket: 4239-58054	App: <del>Not yet assigned</del> 69/762,724
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## OTHER DOCUMENTS

gy			Schluger and Rom, "The Polymerase Chain Reaction in the Diagnosis and Evaluation of Pulmonary Infections," <i>Am. J. Respir. Crit. Care Med.</i> , 152:11-16, 1995 ✓
			Baughman and Liming, "Diagnostic strategies in <i>Pneumocystis carinii</i> pneumonia," <i>Front. Biosci.</i> , 3:e1-12, January 1, 1998 ✓
			Tanabe <i>et al.</i> , "Glycoproteins Composed of Major Surface Immunodeterminants of <i>Pneumocystis carinii</i> ," <i>Infect. Immun.</i> , 57(5):1363-1368, May 1989 ✓
			Theus <i>et al.</i> , "Cytokine responses to the native and recombinant forms of the major surface glycoprotein of <i>Pneumocystis carinii</i> ," <i>Clin. Exp. Immunol.</i> , 109:255-260, 1997 ✓
			Haidaris <i>et al.</i> , GenBank Accession No. AF043102, 6 June 1998.
			Wada <i>et al.</i> , GenBank Accession No. D31920, 22 September 1997
			Wada <i>et al.</i> , GenBank Accession No. D31914, 22 September 1997
			Kovacs <i>et al.</i> , GenBank Accession No. U39660, 29 November 1995
			Edman <i>et al.</i> , GenBank Accession No. U53921, 24 December 1996

EXAMINER: J Goldberg


DATE 5/9/02

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3

<b>INFORMATION DISCLOSURE STATEMENT</b>  <b>BY APPLICANT</b>	Docket: 4239-58054	App: <del>Not yet assigned</del> 01/162729
	Applicant: Kovacs <i>et al.</i>	
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**OTHER DOCUMENTS**

		Mei <i>et al.</i> , "Characterization of major surface glycoprotein genes of human <i>Pneumocystis carinii</i> and high-level expression of a conserved region," <i>Infect. Immun.</i> , 66(9):4268-4273, September 1998 ✓
		Caliendo <i>et al.</i> , "Performance of a PCR assay for detection of <i>Pneumocystis carinii</i> from respiratory specimens," <i>J. Clin. Microbiol.</i> , 36(4):979-982, April 1998 ✓
		Tang <i>et al.</i> , "Determination of copy number of rRNA genes in <i>Pneumocystis carinii</i> f. sp. <i>hominis</i> ," <i>J. Clin. Microbiol.</i> , 36(9):2491-2494, September 1998 ✓
		Lopez <i>et al.</i> , "Europium(III) trisbipyridine cryptate label for time-resolved fluorescence detection of polymerase chain reaction products fixed on a solid support," <i>Clin. Chem.</i> , 39(2):196-201, February 1993 (abstract only)
		Hierholzer <i>et al.</i> , "Detection of adenovirus in clinical specimens by polymerase chain reaction and liquid-phase hybridization quantitated by time-resolved fluorometry," <i>J. Clin. Microbiol.</i> , 31(7):1886-1891, July 1993 (abstract only)
		Eskola <i>et al.</i> , "Detection of Philadelphia chromosome using PCR and europium-labeled DNA probes," <i>Clin. Biochem.</i> , 27(5):373-379, October 1994 (abstract only)
		Chan <i>et al.</i> , "Quantification of polymerase chain reaction products in agarose gels with a fluorescent europium chelate as label and time-resolved fluorescence spectroscopy," <i>Anal. Chem.</i> , 65(2):158-163, January 15, 1993 (abstract only)
		Dahlen <i>et al.</i> , "Detection of human immunodeficiency virus type 1 by using the polymerase chain reaction and a time-resolved fluorescence-based hybridization assay," <i>J. Clin. Microbiol.</i> , 29(4):798-804, April 1991 (abstract only)
		Dahlen <i>et al.</i> , "The use of europium (Eu <sup>3+</sup> ) labelled primers in PCR amplification of specific target DNA," <i>Mol. Cell. Probes</i> , 5(2):143-149, April 1991 (abstract only)

EXAMINER: J. Goldberg

DATE 5/8/02

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4

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**OTHER DOCUMENTS**

<div style="writing-mode: vertical-rl; transform: rotate(180deg);">           JG            ↓         </div>			Guadiz <i>et al.</i> , GenBank Accession No. AF035226, 2 January 1998
			Garbe and Stringer, "Molecular Characterization of Clustered Variants of Genes Encoding Major Surface Antigens of Human <i>Pneumocystis carinii</i> ," <i>Infect. Immun.</i> , 62(8):3092-3101, August 1994
			Theus <i>et al.</i> , "Immunization with the major surface glycoprotein of <i>Pneumocystis carinii</i> elicits a protective response," <i>Vaccine</i> , 16:(11/12):1149-1157, 1998
			Kovacs <i>et al.</i> , "Multiple Genes Encode the Major Surface Glycoprotein of <i>Pneumocystis carinii</i> ," <i>J. Biol. Chem.</i> , 268(8):6034-6040, March 15, 1993
			Chary-Reddy and Graves, "Identification of Extrapulmonary <i>Pneumocystis carinii</i> in Immunocompromised Rats by PCR," <i>J. Clin. Microbiol.</i> , 34(7):1660-1665, July 1996
			Mei <i>et al.</i> , "Characterization of Major Surface Glycoprotein Genes of Human <i>Pneumocystis carinii</i> and High-Level Expression of a Conserved Region," <i>Infect. Immun.</i> , 66(9):4268-4273, September 1998
			Schluger <i>et al.</i> , "Application of DNA Amplification to Pneumocystosis: Presence of Serum <i>Pneumocystis carinii</i> DNA During Human and Experimentally Induced <i>Pneumocystis carinii</i> Pneumonia," <i>J. Exp. Med.</i> , 176:1327-1333, November 1992
			Ortona <i>et al.</i> , "Non specific PCR products using rat-derived <i>Pneumocystis carinii</i> dihydrofolate reductase gene-specific primers in DNA amplification of human respiratory samples," <i>Mol. Cell. Probes</i> , 10:187-190, 1996
			Helweg-Larsen <i>et al.</i> , "Diagnostic use of PCR for detection of <i>Pneumocystis carinii</i> in oral wash samples," <i>J. Clin. Microbiol.</i> , 36(7):2068-2072, July 1998

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J Goldberg

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5/9/02

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5

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<b>INFORMATION DISCLOSURE STATEMENT</b>  <b>BY APPLICANT</b>	Docket: 4239-58054	App: <del>Not yet assigned</del> 09/762724
	Applicant: Kovacs <i>et al.</i>	
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## OTHER DOCUMENTS

gy			De la Viuda <i>et al.</i> , "Use of AmpliWax to optimize amplicon sterilization by isoprosoralen," <i>J. Clin. Microbiol.</i> , 34(12):3115-3119, December 1996 (abstract only)
			Rys and Persing, "Preventing false positives: quantitative evaluation of three protocols for inactivation of polymerase chain reaction amplification products," <i>J. Clin. Microbiol.</i> , 31(9):2356-2360, September 1993 (abstract only)
			Cimino <i>et al.</i> , "Post-PCR sterilization: a method to control carryover contamination for the polymerase chain reaction," <i>Nucleic Acids Res.</i> , 19(1):99-107, January 11, 1991 (abstract only)
			Isaacs <i>et al.</i> , "Post-PCR sterilization: development and application to an HIV-1 diagnostic assay," <i>Nucleic Acids Res.</i> , 19(1):109-116, January 11, 1991 (abstract only)
ET			Kovacs <i>et al.</i> , "Diagnosis of <i>Pneumocystis carinii</i> pneumonia: improved detection in sputum with use of monoclonal antibodies," <i>New England J. Med.</i> , 318(10):589-593, March 10, 1988 ✓
			Lipschik <i>et al.</i> , "Improved diagnosis of <i>Pneumocystis carinii</i> infection by polymerase chain reaction on induced sputum and blood," <i>Lancet</i> , 340:203-206, July 25, 1992 ✓
			Wakefield <i>et al.</i> , "Detection of <i>Pneumocystis carinii</i> with DNA amplification," <i>Lancet</i> , 336:451-453, August 25, 1990 ✓
			Ognibene <i>et al.</i> , "The Diagnosis of <i>Pneumocystis carinii</i> Pneumonia in Patients with the Acquired Immunodeficiency Syndrome Using Subsegmental Bronchoalveolar Lavage," <i>Am. Rev. Respir. Dis.</i> , 129(6):929-932, June 1984 ✓
↓			Bigby <i>et al.</i> , "The Usefulness of Induced Sputum in the Diagnosis of <i>Pneumocystis carinii</i> Pneumonia in Patients with the Acquired Immunodeficiency Syndrome," <i>Am. Rev. Respir. Dis.</i> , 133(4):515-518, April 1986 ✓

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Wakefield *et al.*, "Amplification of mitochondrial ribosomal RNA sequences from *Pneumocystis carinii* DNA of rat and human origin," *Mol. Biochem. Parasitol.*, 43:69-76, 1990 ✓

Santos *et al.*, "Use of the polymerase chain reaction in the diagnosis of leprosy," *J. Med. Microbiol.*, 46:170-172, 1997 ✓

Wada *et al.*, "cDNA Sequence Diversity and Genomic Clusters of Major Surface Glycoprotein Genes of *Pneumocystis carinii*," *J. Infect. Dis.*, 168:979-985, 1993 ✓

Nakamura *et al.*, "Structure of Major Surface Determinants and DNA Diagnosis of *Pneumocystis carinii*," *J. Protozool.*, 36(1):58S-60S, Jan-Feb 1989 ✓

Line and Walzer, "Analysis of a surface antigen of *Pneumocystis carinii*," *J. Protozool.*, 36(1):60S-61S, Jan-Feb 1989 (abstract only)

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